Docket No.: 264982US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:	: EXAMINER: DAVIS, Z.N.
KENICHI KOYAKUMARU, ET AL	: GROUP ART UNIT: 1625
SERIAL NO.: 10/522,195	: U.S. PATENT NO.: 7,560,563
FILED: JUNE 27, 2005	: ISSUED: JULY 14, 2009

FOR: PROCESS FOR PRODUCING 2-SUBSTITUTED PYRIDINE DERIVATIVE

PETITION UNDER 37 C.F.R. §1.705(d) AND
REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

SIR:

Petitioners hereby request reconsideration of the final patent term adjustment for U.S. Patent No. 7,560,563 ("the '563 patent") of 517 days and, in place thereof, Petitioners request that the patent term adjustment be changed to 990 days.

Petitioners contend that the Office erred in determining patent term adjustment published on the face of the '563 patent by not properly accounting for the period of time where issuance of the '563 patent was delayed beyond three years of pendency (35 U.S.C. §154(b)(1)(B)).

Correction of the foregoing error in the patent term adjustment is requested in view of the present Petition including the facts and remarks that follow.

Patent Term Adjustment indicated in the Notice of Allowance and on the '563 Patent:

On March 12, 2009, a Notice of Allowance was issued in U.S. Application Serial No. 10/522,195, which indicated that the determination of patent term adjustment under 35 U.S.C. §154(b) was 517 days. This patent term adjustment represents a 579-day period determined by the Office in which the Office failed to mail of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151 following expiration of 14 months from filing (37 C.F.R. §1.703(a)(1)) from which a total of 62 days have been subtracted in which the Office determined that Petitioner failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application (37 C.F.R. §1.704(a)).

On July 14, 2009, the Office issued U.S. 7,560,563. On the face of the '563 patent a patent term adjustment of 517 days is indicated. Petitioners submit that the Office improperly determined the number of additional days that should have been added for delays beyond three years of pendency (35 U.S.C. §154(b)(1)(B)) for at least two reasons: (1) the Office improperly determined the date of commencement of the National Stage under 35 U.S.C. §371 and (2) the Office misapplied the provision in 35 U.S.C. §154(b)(2) with respect to overlapping delay periods. Accordingly, for the reasons that follow, Petitioners should be entitled to an additional 473 days of patent term adjustment for delays beyond three years of pendency (35 U.S.C. §154(b)(1)(B)) resulting in a total patent term adjustment of 990 days.

Statute relevant to Patent Term Adjustment:

35 U.S.C. §154(b) provides for the patent term guarantees giving rise to an adjustment in patent term.

Specifically, 35 U.S.C. §154(b)(1) provides for the following adjustments to the patent term:

> (1) PATENT TERM GUARANTEES.-
>
> (A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-
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> (i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-
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> the date on which an application was filed under section 111(a) of this title; or
>
> the date on which an international application fulfilled the requirements of section 371 of this title;
>
> (ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;
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> (iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or
>
> (iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.
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> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after

the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO INTERFERENCES, SECRECY ORDERS, AND APPEALS.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to-

(i) a proceeding under section 135(a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

Countering this period is the limitations enunciated in 35 U.S.C. §154(b)(2), which sets forth:

(2) LIMITATIONS.-

(A) IN GENERAL.- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) DISCLAIMED TERM.- No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.-

> (i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.
>
> (ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.
>
> (iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Statute relevant to Commencement of the National Stage for purpose of 35 U.S.C. §154(b)(1)(B):

For purposes of calculating the delay under 35 U.S.C. §154(b)(1)(B), the Office measured application pendency as beginning on June 27, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371(c). However, as detailed below, the relevant statutes and regulations require that when calculating the delay under 35 U.S.C. §154(b)(1)(B) for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application (i.e., not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that

> 3-year period until the patent is issued. 35 U.S.C. § 154(b)(l)(B). (emphasis added)

37 C.F.R. §1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. §154(b)(l)(B):

> (b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... (emphasis added)

35 U.S.C. §§ 371(b) and (f) provide:

> (b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (l) or (2), or under article 39 mea) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

> (f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371 (f).

35 U.S.C. §371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. §371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(l)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19,1970." See 35 U.S.C. §351(a).

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. §371(b) are reproduced below.

Article 22

Copy, Translation, and Fee, to Designated Offices

(1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)

(2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39

Copy, Translation, and Fee, to Elected Offices

(1)(a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from the priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences under the provisions of 35 U.S.C. §371(b). This is the same conclusion as to the timing for commencement of the U.S. National Stage is also summarized in MPEP §1893.01.

> Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). (emphasis added)

In view of the foregoing, the "actual filing date" of a U.S. National Stage application filed under 35 U.S.C. §371, for purposes of calculating the delay under 35 U.S.C. §154(b)(l)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.

Grounds for Request for Reconsideration and Reinstatement of Patent Term Adjustment:

At issue in this case are: (1) the Office's improper determination of the date of commencement of the National Stage under 35 U.S.C. §371 and (2) the Office's misapplication of the provision in 35 U.S.C. §154(b)(2) with respect to overlapping delay periods.

With respect to the Office's improper determination of the date of commencement of the National Stage under 35 U.S.C. §371, Applicants refer to the section above entitled "Statute relevant to Commencement of the National Stage for purpose of 35 U.S.C. §154(b)(1)(B)". This analysis of the relevant law related to the U.S. National Stage application was presented in an "Application for Patent Term Adjustment Under 37 C.F.R. §1.705(d)" on January 8, 2009, in U.S. 10/472,743 (now U.S. 7,465,444). In its decision issued on June 16, 2009, the Office recognized its error in calculating the delay under 35 U.S.C. §154(b)(l)(B) based on the completion of the requirements of 35 U.S.C. §371(c) rather than upon the proper date that is 30

months from the priority date of the international application (i.e., commencement of the National Stage under 35 U.S.C. §371(b)). Thus, in this case as well, it is requested that the Office acknowledge that it is improper to measure application pendency for purposes of 35 U.S.C. §154(b)(1)(B) beginning on June 27, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371(c). The proper date should be 30 months from the priority date of the international application.

The present application is a National Stage (371) of PCT/JP03/09317, filed on July 23, 2003, which claims priority to JP 2002-214097, filed on July 23, 2002. Accordingly, the proper date to measure application pendency for purposes of 35 U.S.C. §154(b)(1)(B) is 30 months from July 23, 2002 - i.e., January 23, 2005.

When using the proper basis date of January 23, 2005, the period of delay under 35 U.S.C. §154(b)(1)(B) begins on January 23, 2008 (i.e., 3 years from commencement of the National Stage under 35 U.S.C. §371(b)) and ends on July 14, 200 (date patent issued). The resulting period of delay under 35 U.S.C. §154(b)(1)(B) is **538 days**.

Turning to the Office's misapplication of the provision in 35 U.S.C. §154(b)(2) related to overlapping periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B). At issue in this case is the Office's misapplication of the provision in 35 U.S.C. §154(b)(2) that states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

On the face of the '563 patent a patent term adjustment of 517 days is indicated. The Office determination of the 517-day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(l)(B), the Office failed to properly allow an adjustment for the time exceeding

three years after the actual filing date of the present application (January 23, 2005 (see discussion above) to the date when the '563 patent issued (July 14, 2009). The correct patent term adjustment for the '563 patent is 340 days.

In this case, the period of patent term adjustment under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) are calculated independently. The following is a summary of the time periods and the number of days of PTA:

35 U.S.C. §154(b)(1)(A)

Plus 579 days from August 27, 2006 (i.e., 14 months from the date of completion of the requirements of 35 U.S.C. §371(c) on June 27, 2005[1]) to March 28, 2008, when Office mailed a Restriction Requirement (i.e., an action under 35 U.S.C. §132) (35 U.S.C. §154(b)(1)(A)(i) and 37 C.F.R. §1.703(a)(1)).

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(A) = **579 days**.

35 U.S.C. §154(b)(1)(B)

Plus 538 days from January 23, 2008 (i.e., 3 years from commencement of the National Stage under 35 U.S.C. §371(b) on January 23, 2005) to July 14, 2009 when the patent issued (35 U.S.C. §154(b)(1)(B)).

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(B) = **538 days**.

[1] In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "8 Delay," the beginning of the relevant period for purposes of calculating "A Delay" is the date on which an international application fulfills the requirements of 35 U.S.C. §371. See 35 U.S.C. §154(b)(l)(A)(i)(II) and 37 C.F.R. §1.702(a)(1).

35 U.S.C. §154(b)(2)(C) correction

Minus 62 days due to Petitioners' failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)) for the period of November 4, 2008 to January 5, 2009.

TOTAL correction to patent term adjustment under 35 U.S.C. §154(b)(2)(C) = **62 days**.

35 U.S.C. §154(b)(2) states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

In *Wyeth v. Dudas*, Civil Action No. 07-1492 (JR) (2008 U.S. Dist. Lexis 76063 (D.D.C., September 30, 2008), copy **enclosed herewith,** the Court issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). Specifically, when determining the overlap defined in 35 U.S.C. §154(b)(2), the *Wyeth* Court held that "[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day" (see page 3, left column, first fully paragraph). In other words, the A delay (i.e., delay under 35 U.S.C. §154(b)(1)(A)) and B delay (i.e., delay under 35 U.S.C. §154(b)(1)(B)) only overlap if the A delay occurs after three years of pendency.

With this proper frame of reference, Petitioners return to the calculation above. In this case, there is an overlap between the A delay and the B delay for the period of January 23, 2008 until March 28, 2008. Thus, the period of reduction under 35 U.S.C. §154(b)(2) is **65 days**.

The resulting calculation of the patent term adjustment for the '563 patent should be as follows:

A delay		B delay		35 U.S.C. §154(b)(2) correction		Applicant Delay		Total PTA
579	+	538	-	65	-	62	=	990

In view of the foregoing and supported by *Wyeth v. Dudas*, Petitioners respectfully request that the Office correct the errors in the patent term adjustment for the '563 patent and properly indicate that the patent term adjustment has been changed to 990 days.

In accordance with the provisions of 37 C.F.R. §1.704(b) and (d), Petitioners submit herewith the requisite fee under 37 C.F.R. §1.18(e). In the event that the Office determines that additional fees are required, it is requested that any underpayment be charged to their undersigned Representative's deposit account (Deposit Account No. 15-0030).

For the foregoing reasons, Petitioners respectfully submit that the Request for Reconsideration of the Patent Term Adjustment of U.S. 7,560,563 should be GRANTED and the patent term adjustment should properly be indicated as 990 days. Early notification of such action is earnestly solicited.

Respectfully submitted,
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